



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,447	09/01/1999	Sachdev S. Sidhu	P1581R2	2633
23552	7590	02/23/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			TRAN, MY CHAU T	
			ART UNIT	PAPER NUMBER
			1639	
DATE MAILED: 02/23/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/380,447

Applicant(s)

SIDHU ET AL.

Examiner

MY-CHAU T TRAN

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-9,11,12,29-33,42,44-49 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) 29,42,48,49 and 52-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-9,11,12,30-33,42,44-47 and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/26/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's response filed 11/2/2004 is acknowledged and entered.
2. Claims 34-41, 43, 50, and 51 were canceled; Claim 31 was amended; and Claims 52-54 added by the amendment filed on 6/14/2004.
3. Claims 2, 5, 6, 10, and 13-28 were canceled and Claims 1, 11, and 12 amended; and Claims 29-51 were added by the amendment filed on 2/26/2004.
4. Claims 1, 3, 4, 7-9, 11, 12, 29-33, 42, 44-49, and 52-54 are pending.

Election/Restrictions

5. Newly submitted claim 42 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The elected invention (Claims 1, 3, 4, 7-9, 11, 12, 29-33, 44-49, and 52-54) is directed to a fusion protein. The newly submitted claim 42 is directed to a phage vaccine. The elected invention and the invention of the newly submitted claim 42 are drawn to distinct inventions, which differ in their structural features. The elected invention comprises a heterologous polypeptide, and a major coat protein. The invention of the newly submitted claim 42 that is directed to a phage vaccine comprises a fusion protein and would also include an additional structure of a pharmaceutical suspension such as a liquid vehicle. Thus these different

Art Unit: 1639

inventions as claimed have different structural features, which differ in functions and modes of operation (MPEP § 806.04, MPEP § 808.01).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 42 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Applicant has elected with traverse the following species for the elected invention (Claims 1, 3, 4, 7-9, 11, 12, 29-33, 44-49, and 52-54) in the reply filed on 4/09/2003, 7/17/2003, and 11/02/2004:

- a. A single specific species of a major coat protein. Applicant elected a filamentous phage of gp VIII, i.e. wild type M13 with the sequence of SEQ ID NO. 2.
- b. A single specific species of variant of the major coat protein. Applicant elected the variant of the major coat protein, i.e. wild type M13 with the sequence of SEQ ID NO. 2, wherein the amino acid and its position are as follows: Position No./Amino Acid: 1/D, 2/K, 3/S, 4/E, 5/K, 6/F, 7/S, 8/R, 9/D, 11/Y, 12/E, 13/A, 14/L, 15/E, 16/D, 17/I, 18/I, 19/T, 20/N, 21/L, 22/F, 23/F, 24/L, 25/L, 26/G, 27/T, 28/V, 29/Y, 30/V.
- c. A single specific species of heterologous protein. Applicant elected an antibody or fragment thereof.
- d. A single specific species of linking peptide. Applicant elected SEQ ID NO. 110.
- e. A single specific species of target. Applicant elected erb 2.

Art Unit: 1639

7. Applicant traversals regarding the species elections of species a) thru c) were acknowledged and addressed in the Office Action mailed 10/03/2003.

8. Applicant's election of species in the reply filed on 11/2/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

9. Claims 29, 48, 49, and 52-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to *non-elected species*, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/02/2004.

10. Claims 1, 3, 4, 7-9, 11, 12, 30-33, and 44-47 are treated on the merit in this Office Action.

Priority

11. This application is a 371 of PCT/US99/16,596 filed 7/22/1999.

Information Disclosure Statement

12. The information disclosure statement (IDS) submitted by applicant, which is filed on 2/26/2004, is acknowledged and considered as noted on PTO-1449 form.

Withdrawn Objection(s) and /or Rejection(s)

13. The objection of claim 11 has been withdrawn in light of applicant's amendments of claim 11.

14. The rejection of claims 1-4, 7-9, and 11-12 under 35 USC 112, first paragraph (written description) has been withdrawn in light of applicant's arguments, see pg 10, lines 1-21, filed 2/26/2004, and amendments of claim 1.

15. The rejections of claim 4 under 35 USC 112, second paragraph, as being incomplete for omitting essential elements has been withdrawn in light of applicant's arguments, see pg. 10, line 29 thru pg. 11, line 4, filed 2/26/2004.

16. The rejection of claims 1-2, 8-9, and 11-12 under 35 USC 102(b) as being anticipated by Scott et al. (*Science*, 1990, 249(4967):386-390) has been withdrawn in light of applicant's arguments and amendment of claim 1.

17. The rejection of claims 1-3, 7, 9, and 11-12 under 35 USC 102(b) as being anticipated by Light, II et al. (US Patent 5,770,356) has been withdrawn in light of applicant's arguments and amendment of claim 1. However, the rejection was rewritten in order to address the newly added claims 30-33, and 44-47.

Art Unit: 1639

18. Please note: Applicant's *specifically* elected species of a fusion protein, which comprises a variant of filamentous phage of gp VIII, i.e. wild type M13 with the sequence of SEQ ID NO. 2 wherein its amino acid variant at the following position are as follows: (Position No./Amino Acid) 1/D, 2/K, 3/S, 4/E, 5/K, 6/F, 7/S, 8/R, 9/D, 11/Y, 12/E, 13/A, 14/L, 15/E, 16/D, 17/I, 18/I, 19/T, 20/N, 21/L, 22/F, 23/F, 24/L, 25/L, 26/G, 27/T, 28/V, 29/Y, 30/V; a linking peptide of SEQ ID NO. 110; and an antibody that binds to erb 2 (see paragraph 6 above). The elected species of a fusion protein was searched and was not found in the prior art. Also, see MPEP § 803.02 (emphasis added):

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. *The prior art search, however, will not be extended unnecessarily to cover all nonelected species.* Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

Thus the search was expanded to non-elected species, which *were* found in the prior art; see rejections below.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1639

20. Claims 1, 3, 4, 7, 9, 11, 12, 30, 31, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Light, II et al. (US Patent 5,770,356).

Light, II et al. disclose a fusion protein (see e.g. Abstract; col. 1, lines 13-17; col. 3, lines 31-38; col. 9, lines 3-5, and 32-35). The fusion protein comprises a heterologous polypeptide attached to the filamentous phage membrane coat protein, and the attachment is through a polypeptide linker at the carboxy terminus of the heterologous polypeptide (see e.g. col. 9, lines 3-5, and 32-35; col. 10, lines 13-34; col. 10, line 58 to col. 11, line 20) (refers to instant claims 1, 3, 12, and 44). The filamentous phage includes phage such as M13, f1, and fd, and membrane coat protein include coat protein such as a gene VIII coat protein (see e.g. col. 10, lines 13-34; col. 13, lines 41-45; col. 22, line 50 thru col. 12) (refers to instant claims 1, and 30). The gene VIII coat protein includes wild type such as SEQ ID NO. 17 (refers to SEQ ID NO. 2) and variant such as SEQ ID NO 14 (see e.g. col. 23, lines 12-49; col. 24, lines 5-12) (refers to claims 1, and 31). The sequence of SEQ ID NO 14 comprises Lys at the 2nd position, Val at the 6th position, and Lys at the 8th position (see e.g. col. 23, lines 12-49; SEQ ID NO 14) (refers to instant claims 4, and 7). The expression vectors of the host cell encode the fusion protein (see e.g. col. 19, lines 6-41) (refers to claims 9, and 11). Thus the fusion protein of Light, II et al. anticipates the presently claimed fusion protein.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1639

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 1, 3, 4, 7-9, 11, 12, 30-33, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Light, II et al. (US Patent 5,770,356) and Marks et al. (US Patent 6,794,128 B2).

Light, II et al. disclose a fusion protein (see e.g. Abstract; col. 1, lines 13-17; col. 3, lines 31-38; col. 9, lines 3-5, and 32-35). The fusion protein comprises a heterologous polypeptide attached to the filamentous phage membrane coat protein, and the attachment is through a polypeptide linker at the carboxy terminus of the heterologous polypeptide (see e.g. col. 9, lines 3-5, and 32-35; col. 10, lines 13-34; col. 10, line 58 to col. 11, line 20) (refers to instant claims 1, 3, 12, and 44). The filamentous phage includes phage such as M13, f1, and fd; and membrane coat protein include coat protein such as a gene VIII coat protein (see e.g. col. 10, lines 13-34; col. 13, lines 41-45; col. 22, line 50 thru col. 12) (refers to instant claims 1, and 30). The gene VIII coat protein includes wild type such as SEQ ID NO. 17 (refers to SEQ ID NO. 2) and variant such as SEQ ID NO 14 (see e.g. col. 23, lines 12-49; col. 24, lines 5-12) (refers to claims

Art Unit: 1639

1, and 31). The sequence of SEQ ID NO 14 comprises Lys at the 2nd position, Val at the 6th position, and Lys at the 8th position (see e.g. col. 23, lines 12-49; SEQ ID NO 14) (refers to instant claims 4, and 7). The expression vectors of the host cell encode the fusion protein (see e.g. col. 19, lines 6-41) (refers to claims 9, and 11).

The fusion protein of Light, II et al. differs from the presently claimed invention by failing to include an antibody as the heterologous polypeptide and the target that binds to the antibody is growth hormones receptors.

Marks et al. disclose an antibody phage display library (see e.g. Abstract; col. 3, lines 54-67; col. 8, lines 39-51). The phage of the library includes phage such as M13, f1, and fd (see e.g. col. 8, lines 52-64). The antibody is fused to the filamentous phage coat protein (see e.g. col. 14, line 60 thru col. 16, line 51). The target includes growth factors receptors (see e.g. col. 4, lines 1-12; col. 11, line 66 to col. 12, line 21). The antibody phage display library provides a system that produces antibodies with affinities that cannot be produced using conventional hydrodome technology (see col. 31, lines 36-38).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an antibody as the heterologous polypeptide and the target that binds to the antibody is growth hormones receptors as taught by Marks et al. in the fusion protein of Light, II et al. One of ordinary skill in the art would have been motivated to include an antibody as the heterologous polypeptide and the target that binds to the antibody is growth hormones receptors in the fusion protein of Light, II et al. for the advantage of providing a system that produces antibodies with affinities that cannot be produced using conventional hydrodome technology (Marks: 31, lines 36-38) since both Light, II et al. and Marks et al.

Art Unit: 1639

disclose polypeptide phage display library (Light: col. 9, lines 3-5, and 32-35; Marks: col. 4, lines 29-32). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Light, II et al. and Marks et al. because Marks et al. the success of an antibody phage display library by example (Marks: col. 31, line 30 to col. 32, line 42).

Response to Arguments

24. Applicant's argument directed to the rejection under 35 USC 102(b) as being anticipated by Light, II et al. (US Patent 5,770,356) was considered but they are not persuasive for the following reasons.

Applicant contends that the fusion protein of Light, II et al. does not anticipate the presently claimed fusion protein because the fusion protein of Light, II et al. comprises additional elements such as a second phage coat protein. Thus the fusion protein of Light, II et al. does not anticipate the presently claimed fusion protein.

It is noted that this rejection as being anticipated by Light, II et al. (US Patent 5,770,356) was rewritten in order to address the newly added claims 30-33, and 44-47.

Applicant's arguments are not convincing since the fusion protein of Light, II et al. does anticipate the presently claimed fusion protein because the presently claimed fusion protein recites, "*A fusion protein comprising*". The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements. (See MPEP 2111.03) Thus, the presently claimed fusion protein does not exclude the additional elements recited by the fusion protein of

Art Unit: 1639

Light, II et al. Therefore the fusion protein of Light, II et al. does anticipate the presently claimed fusion protein, and the rejection is maintained.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
February 21, 2005



PADMASHRI PONNALURI
PRIMARY EXAMINER